UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

PAUL HAYDEN, et al.,

Plaintiffs,

v.

PORTOLA PHARMACEUTICALS, INC., et al.,

Defendants.

Case No. 20-cv-00367-VC

**ORDER GRANTING IN PART AND DENYING IN PART DEFENDANTS' MOTION TO DISMISS SECOND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT**

Re: Dkt. No. 119, 138

Investors in Portola Pharmaceuticals bring this suit alleging that the company made misleading statements in violation of the Exchange Act by repeatedly overstating its 2018 revenue. Because Portola made a public stock offering that incorporated those revenue statements, the plaintiffs also allege that Portola and the companies that underwrote the public offering violated the Securities Act. For the reasons explained below, accepting as true the well-pled allegations in the complaint, the plaintiffs have articulated a highly plausible theory of securities fraud. Nonetheless, the motion to dismiss must be granted as to the Exchange Act claims, because the plaintiffs have not adequately alleged loss causation. The motion to dismiss is denied as to the Securities Act claims. Dismissal of the Exchange Act claims is with leave to amend, and any amended complaint is due within 21 days of this order. Because this decision relies only on allegations and arguments raised in the complaint and opposition brief, the defendants' motion for leave to file a sur-reply (Dkt. No. 138) is denied.

## Exchange Act Claims

To state a claim under Section 10(b) and Rule 10b-5 of the Exchange Act, the plaintiffs must allege a false statement (meaning a material misrepresentation or omission), scienter, and a causal relationship between the plaintiffs' economic loss and the false statement. Under the Private Securities Litigation Reform Act, both the false statement and scienter must be pled with particularity. *City of Dearborn Heights Act 345 Police & Fire Retirement System v. Align Technology, Inc.*, 856 F.3d 605, 613 (9th Cir. 2017) (*Align*).

Both sides treat the alleged false statements as statements of opinion. When a statement of opinion is involved, additional requirements apply. If plaintiff claims that an opinion is an affirmative misrepresentation, the complaint must allege either that (i) the belief is both objectively untrue and was not subjectively held by the speaker; or (ii) the opinion statement included within it a false statement of a material fact. If the plaintiff claims that an opinion was misleading because of an omission, the complaint must allege that the defendants omitted facts that are significant enough to make the opinion statement misleading to a reasonable person reading the statement. *Id*. at 615-16 (citing *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015)). The plaintiffs pursue an omission theory, alleging primarily that Portola's statements of its estimated revenues for prior periods were misleading because the defendants omitted material facts that, if disclosed, would have caused investors to seriously doubt the validity of those estimates.

To understand the omission these plaintiffs are alleging, it is first necessary to understand both Portola's business model and its financial reporting obligations as a publicly traded company. Prior to being purchased by Alexion (which is now owned by AstraZeneca), Portola was a small pharmaceutical start-up company. In 2018 the FDA approved Portola's second-ever product, a coagulant called Andexxa. Andexxa is used to stop emergency bleeding in patients who are being treated with certain kinds of blood thinners. Because there was no drug already approved to treat these rare but life-threatening bleeds, the FDA approved Andexxa through an expedited process as an "orphan drug." That meant Portola did not need to produce proof that the drug actually worked in sick patients; only that it was safe and caused a chemical change in the

blood of healthy volunteers. Although Andexxa remains the only FDA-approved drug for treating this class of bleeds, another drug called Kcentra has long been used as an off-label treatment.

Portola began selling a limited supply of Andexxa in May 2018. This first-generation product had a shelf life of 6 to 12 months. In December 2018, the company announced that it had received FDA approval for a scaled-up manufacturing process that would produce much larger volumes of the drug. This was a second-generation product with a longer shelf life, remaining usable for 36 months after production. However, as alleged in the complaint, Portola did not start shipping the longer-dated product until November 2019.

According to the complaint, Portola faced two major challenges in achieving widespread use of Andexxa. The first challenge was the price tag. During the relevant period Portola was charging between $24,750 and $49,500 per dose. By comparison, Kcentra was available for less than $10,000 per dose. At least one former Andexxa salesperson allegedly told the plaintiffs' attorneys that the price was a "shock" to hospitals considering stocking the drug, and several others reported similar difficulties in convincing hospitals to make such a big-ticket purchase. The second challenge was the inherently unpredictable nature of the condition Andexxa is designed to treat. As the complaint describes it, these kinds of bleeds are "outlier" emergencies that only occur in a small percentage of patients who are taking a particular class of blood thinners. That reality further complicated the financial decision facing hospitals, because hospitals only recoup the cost of a drug when it gets used to treat a patient. Unlike a drug that would be prescribed to a patient for regular use in an outpatient setting, or routinely used for a wide variety of patients in the hospital, Andexxa would not be needed frequently or with any kind of predictability. That meant a hospital would pay the exorbitant price to stock Andexxa without knowing when, if ever, it could recoup that cost.

Presumably because of these challenges, Portola offered customers a very generous return policy for Andexxa. Hospitals could return unopened doses of the drug at any time in a nine-month window. That window opened three months before the dose's expiration date and

closed six months after the expiration date. For the first-generation product sold in 2018 with a maximum 12-month shelf life, that meant a purchaser could theoretically return the drug 18 months after it was first purchased, well into calendar year 2020. Additionally, the policy applied regardless of whether a hospital had purchased the drug directly from Portola or from a specialty distributor. In fact, distributors could also return any doses they had not managed to sell to hospitals.

This return policy had important ramifications for Portola's financial reporting obligations. Like all publicly traded companies, Portola was required to report its financial results, including revenues, on a quarterly and annual basis. The SEC requires that companies' statements of revenue comply with "generally accepted accounting principles," known as "GAAP." 17 C.F.R. § 244.100. Most relevant to this case, a new GAAP rule ("ASC 606") that went into effect in 2018 set a standard for how companies report revenues from contracts for the sale of goods.[1]

In many situations, a company's expected revenue from the sale of a given product is something less than the listed sales price for that product. That's because various provisions in the contract—like rebates or return polices—might force the company to give some money back to the customer. In general terms, under ASC 606 companies can only count money from sales as "revenue" when they can be pretty sure that they will not end up giving that money back. Moreover, this means any stated revenue is an estimate, because it reflects the company's expectation of how much money it will get to keep, not the actual amount of money it has collected to date.

Speaking more technically, and as relevant to the allegations in the complaint, a company can only report revenue from sales when it is able to conclude that it is not likely to suffer a

[1] *See* Financial Accounting Standards Update No. 2014-09, *Revenue from Contracts with Customers*, available at https://www.fasb.org/cs/ContentServer?cid=1176164076069&d=Touch&pagename=FASB%2FDocument_C%2FDocumentPage.

significant reversal. ASC 606-10-05-4.[2] Moreover, a company can only reach that conclusion after first analyzing a specified set of factors, including historical data on returns from that product or similar products, how long it will be before any uncertainty is resolved, and the relevance of circumstances beyond the company's control. ASC 606-10-32-12. If the company is not able to conclude that revenue from a particular sale is likely to stick—either because it lacks enough information to make a sufficiently reliable estimate, or because the information available suggests the risk of a significant reversal—it cannot report revenue from that sale.

One way companies can comply with ASC 606 is by stating "reserves." As explained in the complaint, a reserve is just an estimated dollar amount provided in a financial report that represents the company's expectation of how much money it will be required to give back to customers for returns, rebates, etc. For example, imagine that in one year a publicly traded company sold 100 t-shirts for $10 apiece and, based on its prior experience selling shirts, expected that 20% of the shirts sold would get returned for a full refund. To comply with GAAP, the company would report $800 in net revenue (that is, net of a $200 reserve for returns). That would indicate to outside observers that regardless of the number of shirts actually sold, the company could only expect to keep around $800 in revenue. In the language of GAAP, the t-shirt company is estimating that a significant reversal of the $800 due to unexpected additional returns is not probable.

Like the hypothetical t-shirt company, Portola reported its revenue from Andexxa and its other product, Bevyxxa, net of reserves for expected returns.[3] On March 1, 2019, the company filed its annual financial report for 2018 ("Form 10-K 2018"). Portola reported in that filing that it had earned $23.995 million in net revenue from Andexxa sales in 2018. Although the form stated that revenue was net of a return reserve, it did not disclose the actual dollar amount of that

[2] The actual language of the rule uses a confusing double negative: "The estimated amount of variable consideration will be included…only to the extent that it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved."
[3] The company also made reserves and reduced its net revenue to account for other factors not particularly relevant to this case.

reserve. That's as if the hypothetical t-shirt company reported $800 in net revenue without saying it had reserved $200 for returns. While that in itself is apparently not a GAAP violation, an investor reading Portola's Form 10-K 2018 would not know how much Andexxa the company actually sold in 2018 or, importantly for this case, what percentage of that sales revenue the company expected to need to give back for returned product before the return window closed in 2020.

It was not until February 28, 2020 that Portola disclosed the dollar amount of return reserves it had taken for product sold in 2018. This disclosure came in the company's annual report for 2019 ("Form 10-K 2019"). That document included a table showing return reserves taken for Andexxa in 2018 as well as "payments and customer credits issued" for returns actually made as of December 31, 2018. *See* Dkt. 113-4 at 3.[4] That table shows that in 2018, the dollar amount Portola actually reserved for product returns was $2.611 million. That is, the company had estimated internally in 2018 that when the return window ultimately closed for doses sold in 2018, $2.611 million worth of Andexxa would have been returned for a full refund while $23.995 million worth of Andexxa (the amount reported as net revenue) would not have been returned. And as mentioned above, the return window for products sold in 2018 would typically not close until some point in 2020.

The same table reported a second significant fact, also disclosed for the first time in the Form 10-K 2019 that was filed on February 28, 2020. The table shows that as of December 31, 2018, Portola had already paid customers $2.312 million for returned product. That is, of the $2.611 million Portola expected to pay back for returns by mid-2020, the company had paid back all but $299 thousand before the first day of 2019. With well over a year left in the return window, nearly 90% of the reserve had already been depleted.

Portola's omission of this key fact—that only $299 thousand of its $2.611 million in

[4] Technically, the numbers reported in that table represent reserves taken for all products sold—both Andexxa and Bevyexxa. However, as is explained below, Andexxa accounted for 99% of Portola's revenue in 2018, meaning that the vast majority of the reserves taken and the product returned would also have been Andexxa.

return reserves for 2018 remained by the end of 2018—forms the core of the plaintiffs' Exchange Act claims. The theory of misrepresentation by omission goes as follows: Portola repeatedly stated net revenue for 2018 and claimed that its revenue statement complied with GAAP. That revenue statement was an estimate and therefore an opinion subject to *Align* and *Omnicare*. Because the revenue stated was net of a reserve for expected returns, the amount of reserve taken *and* the amount remaining after accounting for returns already made are material bases for the company's estimate of the amount for 2018 revenue it would ultimately get to keep. Perhaps the company was not required to disclose these numbers if reserves were depleting at the rate the company expected, but in this case the omission was material because no reasonable investor would have expected the $23.995 million in revenue to hold when $2.312 million had already been paid in returns and only $299 thousand remained to cover returns that would be made in 2019 and 2020. In light of Andexxa's twin challenges regarding price and unpredictable use, and given the company's carte-blanche return policy, this theory of a material omission is highly plausible.

To be sure, *Align* and *Omnicare* set a tall order for plaintiffs attempting to plead that a statement of opinion was misleading by omission. It is not enough to allege the existence of some fact that cuts against the accuracy of the expressed opinion. *Align*, 856 F.3d at 615. The nature of an opinion is that it includes some uncertainty, and any given fact might suggest a different possible outcome. Instead, to state a claim, a plaintiff must plausibly allege that the omitted facts "conflict with what a reasonable investor would take from the statement itself." *Id.* (quoting *Omnicare*, 575 U.S. at 189). If the person or entity making the statement knew something that would render the stated opinion objectively inaccurate, they have an obligation to disclose that fact. *See also Retail Wholesale & Department Store Union Local 228 Retirement Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1278 (9th Cir. 2017) ("An actionable omission claim arises only when disclosure is necessary to make the statements made, in light of the circumstances under which they were made, not misleading.") (citing 17 C.F.R. § 240.10b–5(b)).

Here, the fact that Portola's reserves for 2018 product were almost depleted by the start

of 2019 plainly contradicts the company's statement that as of March 1, 2019 it could expect to keep $23.995 million in revenue from 2018 sales of Andexxa. Portola had originally predicted that about 10% of its gross revenue from Andexxa ($2.611 million of at least $26.606 million in sales) would get returned over the course of the following 18 months. In fact, about 9% got returned within just a few months. In the face of those facts, a stated expectation that not much more than 1% of product—the remaining $299 thousand—would be returned during well over a year of remaining eligibility crosses the line from irrationally hopeful to grossly inaccurate.

In their briefs and at the hearing on this motion, the defendants repeatedly made two arguments to support the proposition that failing to disclose the depleted reserve did not constitute a material omission. First, they contended that the presence of a positive amount left in the reserve account by the end of 2018 actually indicates that the company over-reserved for returns. But this argument itself stems from a mistaken interpretation of the table published in Portola's Form 10-K 2019. That table clearly states that $299 thousand was the "balance at December 31, 2018." That is, $299 thousand was left after accounting for product returned before that date—not accounting for product returned on or after January 1, 2019. Thus, as stated in the table, the amount remaining in the reserve is not an "extra cushion," but rather an alarmingly small remainder.

Second, the defendants posited that the small amount left at the end of 2018 does not support an inference that Portola knew when it made its original reserve estimate that it was under-reserved. After all, the point of taking reserves is to hedge uncertainty, and no company has a crystal ball. But that argument frames the issue around the wrong point of reference. What matters is what Portola knew when it made the allegedly misleading statement of revenue: on March 1, 2019, when the company filed its Form 10-K 2018. That is the day Portola told the investing public that its 2018 revenue from Andexxa was close to $24 million and that, in the company's best estimation, that number was not likely to be subject to a significant reversal. By that date, the company obviously knew that the vast majority of its returns reserve had already been depleted by actual returns. Given the singular importance of Andexxa, the limited number

of sales, and the high price of each dose, there is no reason to think the company was not tracking returns in real time. Even defense counsel appeared to concede this at the hearing on this motion. Because the plaintiffs have alleged with particularity that Portola stated its estimated revenue while omitting this material fact (a fact that would have shone a light on how inaccurate the estimate was), they have satisfied the first element of an Exchange Act claim.

This brings us to the issue of scienter. To fulfill this element, the complaint must state with particularity facts giving rise to a strong inference that the individual defendants made the false or misleading statements either intentionally or with deliberate recklessness. *Reese v. Malone*, 747 F.3d 557, 568-69 (9th Cir. 2014) (overruled on other grounds by *Align*, 856 F.3d 605). One way a plaintiff can meet this requirement is by alleging that due to each defendant's role in the company it would be "absurd" to suggest that they did not know about the relevant facts that rendered their statements misleading. *Id*. at 575-76. When the challenged statements involve the company's core operations, that showing can be made without alleging any specific facts that an individual officer actually knew about the particular fact—knowledge is essentially assumed. *See id.* at 576 (citing *Berson v. Applied Signal Technology*, 527 F.3d 982 (9th Cir. 2008)).

As already noted, it would be absurd to think that any of Portola's officers and directors did not know about the rate of Andexxa returns or its relevance to the company's revenue statements. The individually named defendants are, respectively the company's CEO, CFO, Chief Commercial Officer, Chairman of the Board of Directors, and Directors. All except Koenig, the Chief Commercial Officer, personally signed the Form 10-K 2018. Collectively, these defendants were responsible for the financial wellbeing of the company, which in turn depended almost entirely on the commercial success of Andexxa. The Form 10-K 2018 shows that more than 99% of the company's net product revenues for the year came from Andexxa ($23.995 million of $24.1 million), and product revenues accounted for 60% of the company's total net revenue for the year (with the remainder coming from collaborations and licensing). *See* Dkt. No. 130-7 at 48. On top of that, CEO Garland's public statements emphasized the

importance of Andexxa to the company's financial success. On March 1, 2019, the day the Form 10-K 2018 was filed, he highlighted the fact that the company kept close track of data on Andexxa sales and utilization, including having "visibility" into shipments from distributors to hospitals and auditing the medical records of patients treated with Andexxa. And in June of that year, he told analysts on a conference call that the company was and would remain "focused on Andexxa." The price of the product was high, and the number of sales relatively small. In light of those facts, any suggestion that the company's officers and directors were not aware of such basic information as how much product had been returned by the end of 2018 and how that compared to the reserves taken for 2018 sales would be absurd.

But despite alleging a misleading statement and scienter, the current complaint does not sufficiently allege loss causation. To satisfy this element, the plaintiffs must allege that the revelation of the identified omission was a substantial factor in cause the company's stock price to decline, thereby causing an economic loss for its investors. *Nuveen Municipal High Income Opportunity Fund v. City of Alameda, California*, 730 F.3d 1111, 119 (9th Cir. 2013). This is frequently achieved by identifying the date that "the truth is revealed" through some public announcement and then describing how much the stock dropped thereafter, often bolstered by statements from analysts citing the revelation as the cause for investor concern. *See, e.g., In re Daou Systems*, 411 F.3d 1006, 1026 (9th Cir. 2005).

The current complaint fails to allege that the revelation of the previously omitted reserve numbers caused the plaintiffs any economic loss. As a practical matter, it appears that when the plaintiffs shifted the focus of their lawsuit from more general statements about demand and future growth to the reserve depletion issue, they forgot to update the section on loss causation from the prior version of the complaint.[5] All of the substantive allegations related to loss

[5] Although this ruling focuses on the allegations about the clearest examples of false statements—those relating to 2018 revenue while omitting information about the depleted reserves—to the extent these allegations are true, they would tend to increase the probability that some of the other statements regarding demand and future growth were also false when made. In other words, assuming the defendants knew the return reserve had been depleted so rapidly and that more returns were likely, this suggests that the defendants knew they had a serious problem

causation focus on the company's announcements on January 9 and February 26, 2020 of lower-than-expected 2019 sales, flat demand, and lower utilization. Although the January announcement included the news that Portola took a $5 million charge to add to its return reserves for both "catch up" and to account for expected future returns (which perhaps could be characterized as a partial revelation), nothing in the announcement ties that charge directly to product sold in 2018 or would give an investor cause to specifically question the company's prior statements regarding its 2018 revenue. Moreover, the same section alleges that investors' concerns over those two announcements caused Portola's stock to drop; it does not state that any further drop was caused by the more specific revelation of the depleted reserve for returns of 2018 product. Complaint at ¶¶ 250-51, 257-58. Nor could it, because as noted above, the depleted reserve was first revealed on February 28, 2020—two days after the end of the proposed class period on February 26, 2020. In sum, although the earlier announcements are relevant to the plaintiffs' new theory (particularly the part about the $5 million "catch up" charge), overall the complaint does not present a coherent narrative on loss causation stemming from the failure to disclose throughout 2019 how depleted the reserve had become for product sold in 2018.

**Securities Act Claims**

To state a claim for violation of Sections 11 and 12 of the Securities Act, a plaintiff must allege a material misrepresentation or omission in a registration statement or prospectus filed in connection with a public stock offering. 15 U.S.C. §§ 77k(a), 77l(a); *see Rubke v. Capitol Bancorp Ltd.*, 551 F.3d 1156, 1161 (9th Cir. 2009). Unlike Exchange Act claims, the Securities Act claims do not require a plaintiff to allege scienter or loss causation.[6] *In re Daou Systems,*

with the commercial viability of their main product. Although the allegations with respect to statements about growth and demand are not particularly strong taken on their own, they become stronger when considered in conjunction with the allegedly misleading omissions about the company's revenues.

[6] These sections do provide an affirmative defense whereby, at later stages of the litigation, a defendant may reduce its liability by showing that the plaintiffs' losses were caused by something other than the misrepresentation. 15 U.S.C. §§ 77k(e), 77l(b).

*Inc.*, 411 F.3d 1006, 1027 (9th Cir. 2005).

Portola undertook a public stock offering in August 2019, between the time it had announced its 2018 revenues and when it revealed its depleted return reserve in February 2020. The offering was underwritten by defendants Goldman Sachs, Citigroup, Cowen, William Blair, and Oppenheimer. The registration statement and prospectus filed by Portola in connection with the public offering incorporated by reference several prior filings that stated 2018 revenue without any accompanying disclosure of the depleted return reserves. This included the company's Form 10-K 2018. The registration statement therefore contained a materially misleading statement by means of omission, and the motion to dismiss the Securities Act claims is denied.

* * * *

Because the plaintiffs have successfully stated a Securities Act claim, and because they will almost certainly be able to fix the loss causation allegations for their Exchange Act claim, this case will begin to move forward. A case management conference is scheduled for Wednesday, September 1, 2021 at 2:00 p.m. A joint case management statement is due August 25, and it should include a proposed schedule for litigating the case to trial.

**IT IS SO ORDERED.**

Dated: August 10, 2021

VINCE CHHABRIA
United States District Judge